AMENDMENTS TO THE CLAIMS

The listing of claims will replace all prior versions, and listings, of claims in the application:

1-4. (canceled)

5. (currently amended) A process for preparing ondansetron hydrochloride monohydrate comprising the steps of:

a) contacting crystals of ondansetron hydrochloride dihydrate with a mixture of from about 4% to about 50% water in ethanol to convert the crystals of ondansetron hydrochloride dihydrate to crystals of ondansetron hydrochloride monohydrate,

b) separating the crystals of ondansetron hydrochloride monohydrate from the ethanol:water mixture, and

c) recovering the crystals of ~~as~~ ondansetron hydrochloride monohydrate.

6. (original) The process of claim 5 wherein the contacting occurs at the reflux temperature of the ethanol:water mixture.

7. (original) The process of claim 5 wherein the dihydrate and monohydrate are denominated Form A expressing that their crystal structures are the same.

8. (Currently amended) A process for preparing ondansetron hydrochloride dihydrate Form A comprising the steps of:

a) providing crystals of ~~the~~ ondansetron hydrochloride monohydrate,

b) hydrating the crystals under an atmosphere of 50% relative humidity or greater to form dihydrate crystals containing about 10% water, and

c) collecting the dihydrate~~d~~ crystals ~~containing about 10% water of~~ by filtration ~~crystallization~~.

9. (canceled)

10. (currently amended) A process for preparing ~~the~~ ondansetron hydrochloride Form A containing between about 5% water and 10% water, comprising the steps of:

a) suspending ondansetron free base in a liquid medium selected from the group consisting of absolute ethanol, a mixture of ethanol and isopropanol, and chloroform,

b) dissolving the free base by adding anhydrous HCl to the suspension,

c) crystallizing ondansetron hydrochloride Form A from the liquid medium, and

d) separating the ~~crystals~~ crystalline ondansetron hydrochloride Form A from the liquid medium.

11. (original) The process of claim 10 wherein the liquid medium is absolute ethanol.

12. (original) The process of claim 10 wherein the HCl is added in an amount of 1 ± 0.1 equivalent with respect to the ondansetron free base.

13. (Currently amended) The process of claim 10 wherein the anhydrous HCl is ~~added as~~ a gas.

14. (original) The process of claim 10 wherein the anhydrous HCl is added in solution in an inert organic solvent.

15. (Currently amended) The process of claim ~~10~~ 11 wherein the absolute ethanol is heated to hasten the dissolution of the ondansetron free base.

16. (currently amended) A process for preparing ~~the~~ ondansetron hydrochloride Form A containing between about 5% water and 10% water, comprising the steps of:

a) dehydrating crystals of ondansetron hydrochloride dihydrate by contacting the crystals with a liquid medium selected from the group consisting of ethanol, mixtures of ethanol and water, toluene and mixtures of ethanol and toluene,

b) separating the liquid medium from the crystals to obtain ondansetron hydrochloride Form A, and

c) collecting the crystals of ondansetron hydrochloride Form A.

17. (original) The process of claim 16 wherein the crystals are mechanically agitated during dehydration.

18. (original) The process of claim 17 wherein the mechanical agitation is sonication.

19. (original) Anhydrous ondansetron hydrochloride.

20. (original) Anhydrous ondansetron hydrochloride Form B.

21. (previously presented) Anhydrous ondansetron hydrochloride polymorphic Form B characterized by powder X-ray diffraction peaks at 10.5, 11.9, 13.0, 13.5, and 15.1 ±0.2 degrees two-theta.

22. (Currently amended) The anhydrous ondansetron hydrochloride polymorphic Form B of claim 21 characterized by powder X-ray diffraction peaks at 10.5, 11.9, ~~10.5,~~ 13.0, 13.5, 15.1, 20.9, 22.7, 24.0, and 25.7 ±0.2 degrees two-theta.

23. (canceled)

24. (canceled)

25. (previously presented) A process for preparing the ondansetron hydrochloride of claim 21 or 22 by treating ondansetron hydrochloride with a dry alcohol.

26. (original) The process of claim 25 wherein the solvent is absolute ethanol.

27. (previously presented) The process of claim 25 wherein the ondansetron hydrochloride that is treated with dry alcohol is Form A.

28. (original) The process of claim 25 wherein the treatment is carried out at about 20°C.

29. (previously presented) The process of claim 28 wherein the ondansetron hydrochloride that is treated with dry alcohol is Form A.

30. (original) The process of claim 25 wherein the alcohol is ethanol, isopropanol, 1-butanol or a mixture of thereof.

31. (previously presented) The process of claim 30 wherein the ondansetron hydrochloride that is treated with dry alcohol is Form A.

32. (Currently amended) A process of preparing the ondansetron hydrochloride of claim 21 or 22 by treating ondansetron ~~HCl~~ hydrochloride with a dry organic solvent.

33. (original) The process of claim 32 wherein the solvent is absolute ethanol.

34. (Currently amended) The process of claim 32 wherein the ondansetron hydrochloride that is treated ~~with dry alcohol~~ is Form A.

35. (original) The process of claim 32 wherein the solvent is a ketone.

36. (Currently amended) The process of claim 35 wherein the ondansetron hydrochloride that is treated with ketone ~~dry alcohol~~ is Form A.

37. (original) The process of claim 32 wherein the treatment is carried out at about 20°C.

38. (Currently amended) The process of claim 37 wherein the ondansetron hydrochloride that is treated ~~with dry alcohol~~ is Form A.

39. (previously presented) The anhydrous ondansetron hydrochloride polymorphic Form B of claim 21 having a particle size below about 300 microns.

40. (canceled)

41. (previously presented) The anhydrous ondansetron hydrochloride polymorphic Form B of claim 21 having a particle size below about 200 microns.

42. (canceled)

43. (previously presented) The anhydrous ondansetron hydrochloride polymorphic Form B of claim 21 having a particle size below about 40 microns.

44. (canceled)

45. (previously presented) The anhydrous ondansetron hydrochloride polymorphic Form B of claim 21 with a water content up to about 2%.

46. (previously presented) A process for preparation of anhydrous ondansetron hydrochloride polymorphic Form B characterized by powder X-ray diffraction peaks at 10.5, 11.9, 13.0, 13.5, and 15.1 ±0.2 degrees two-theta comprising reacting HCl gas with a toluene solution of ondansetron base.

47. (previously presented) The process of claim 46 wherein the ondansetron base is dissolved at the reflux temperature of toluene.

48. (previously presented) The process of claim 46 wherein HCl gas is bubbled into the toluene solution of ondansetron base.

49. (previously presented) Ondansetron hydrochloride Form C, characterized by strong powder X-ray diffraction peaks at 6.3 and 24.4 ±0.2 degrees two-theta and other peaks at 9.2, 10.2, 13.1 and 16.9 ±0.2 degrees two-theta.

50. (previously presented) Ondansetron hydrochloride Form C, characterized by powder X-ray diffraction peaks at 6.3, 9.2, 10.2, 13.1, 16.9 and 24.4 ±0.2 degrees two-theta.

51. (original) A process for preparation of the product of claim 49 or 50 which comprises the steps of:
    a) dissolving ondansetron base in ethanol,
    b) adding an ethanolic solution of hydrochloride,
    c) filtering, and
    d) evaporating the mother liquor.

52. (previously presented) Ondansetron hydrochloride Form D, characterized by powder X-ray diffraction peaks at 8.3, 14.0, 14.8 and 25.5 ±0.2 degrees two-theta.

53. (previously presented) A process for preparing the ondansetron hydrochloride Form D of claim 52 comprising the steps of:
    a) melting ondansetron hydrochloride in the presence of xylene; and

b) adding the melt to ethanol.

54. (Currently amended) The process of claim 53 wherein the ondansetron hydrochloride is ondansetron hydrochloride Form A ~~is melted in the presence of xylene~~.

55. (Currently amended) The process of claim 53 wherein the ethanol is at a temperature of from about -15°C~~.~~ to about room temperature.

56. (original) The process of claim 55 wherein the ethanol is at a temperature of about -10°C.

57. (Currently amended) Ondansetron hydrochloride Form E, characterized by a strong powder X-ray diffraction peak at 7.4 degrees two-theta and ~~other typical~~ peaks at 6.3, 10.5, 11.2, 12.3, 13.0, 14.5, 15.9, 17.0, 20.1, 20.8, 24.5, 26.2 and 27.2 ±0.2 degrees two-theta.

58. (previously presented) Ondansetron hydrochloride Form E, characterized by powder X-ray diffraction peaks at 6.3, 7.4, 10.5, 11.2, 12.3, 13.0, 14.5, 15.9, 17.0, 20.1, 20.8, 24.5, 26.2 and 27.2 ±0.2 degrees two-theta.

59. (original) A process for preparation of the product of claim 57 or 58 which comprises the step of treating ondansetron hydrochloride in isopropanol.

60. (original) The process of claim 59 wherein the ondansetron hydrochloride is Form A.

61. (original) The process of claim 59 wherein the temperature of the isopropanol is from about room temperature to about reflux temperature.

62. (original) Ondansetron hydrochloride isopropanolate.

63. (original) Ondansetron hydrochloride Form E isopropanolate.

64. (original) Ondansetron hydrochloride Form E mono-isopropanolate.

65. (original) Ondansetron hydrochloride Form E hemi-isopropanolate.

66. (original) Ondansetron hydrochloride Form E having a water content of up to about 10%.

67. (previously presented) Ondansetron hydrochloride Form H, characterized by powder X-ray diffraction peaks at 7.8, 14.0, 14.8 , 24.7 and 25.6 ±0.2 degrees two-theta.

68. (Currently amended) A process for preparing the ondansetron hydrochloride Form H of claim 67 which comprises the steps of:

a) suspension of ondansetron base in absolute ethanol;

b) adding an ethanol solution of hydrochloric acid to the suspension;

c) precipitating ondansetron hydrochloride Form H by adding ether to the suspension ~~with the addition of ether~~; and

d) isolating the ~~product~~ ondansetron hydrochloride Form H.

69. (original) The process of claim 68 wherein the ether is methyl tert-butyl ether or diethyl ether.

70. (original) The process of claim 68 wherein the ether is dry.

71. (canceled)

72. (previously presented) Ondansetron hydrochloride methanolate.

73. (original) Ondansetron hydrochloride methanolate Form I.

74. (Currently amended) Ondansetron hydrochloride Form I, characterized by a strong XRD peak at 25.0 [[+]] ±0.2 degrees two-theta and other XRD peaks at 8.2, 9.3, 9.9, 11.1 and 24.9 ±0.2 degrees two-theta.

75. (Currently amended) Ondansetron hydrochloride Form I, characterized by a strong XRD peak at 25.0 ±0.2 degrees two-theta and other XRD peaks at 8.2, 9.3, 9.9, 11.1, 13.9, 16.0, 17.0, 21.0, 22.6, 25.8, 27.3 and 28.0 ±0.2 degrees two-theta.

76. (Currently amended) Ondansetron hydrochloride Form I, characterized by a strong XRD peak at 25.0 ±0.2 degrees two-theta and other XRD peaks at 6.9,

8.2, 8.7, 9.1, 9.3, 9.9, 11.1, 11.6, 13.8, 16.1, 16.9, 17.9, 21.1, 22.7, 25.7, 26.6, 27.4 and 27.9 ±0.2 degrees two-theta.

77. (original) A process for crystallizing ondansetron hydrochloride Form I comprising exposing ondansetron hydrochloride to methanol vapor.

78. (original) The process of claim 77 wherein the exposure is for a period of about three weeks or less.

79. (original) The process of claim 77 wherein the exposure is at room temperature.

80. (original) The process of claim 77 wherein ondansetron hydrochloride Form A is exposed to methanol vapor.

81. (original) The process of claim 77 wherein ondansetron hydrochloride Form B is exposed to methanol vapor.

82. (Currently amended) A process for preparing anhydrous ondansetron hydrochloride Form B comprising the steps of:

a) dissolving ondansetron base in absolute ethanol;

b) adding to the dissolved ondansetron base an ethanol/hydrochloric acid solution to obtain ondansetron hydrochloride Form B; and

c) collecting by filtration the ondansetron hydrochloride Form B ~~filtering~~.

83. (original) The process of claim 82 wherein the ethanol is substantially dry.

84. (original) The process of claim 82 wherein the ondansetron base and the ethanol/hydrochloric acid solution are mixed at room temperature.

85. (Currently amended) The process of claim 82 wherein the mixture of ondansetron base is heated at ~~to~~ reflux temperature.

86. (original) The process of claim 82 wherein the ondansetron base and the ethanol/hydrochloric acid solution are mixed for a period of about 30 to about 70 hours at room temperature.

87. (Currently amended) Ondansetron hydrochloride in particle form having ~~with a particle size distribution of~~ 100% of the particles ~~particle size~~ below about 100 microns ~~and a pharmaceutically acceptable carrier~~ in size.

88. (Currently amended) Ondansetron hydrochloride in particle form having ~~with a particle size distribution of~~ 100% of the particles ~~particle size~~ below about 50 microns ~~and a pharmaceutically acceptable carrier~~ in size.

89. (Currently amended) A pharmaceutical composition comprising ondansetron ~~Ondansetron~~ hydrochloride in particle form ~~solid state~~ and a pharmaceutically acceptable carrier, wherein the ondansetron hydrochloride in particle form has ~~with a particle size distribution of~~ 100% of the particles ~~particle size~~ below about 200 microns ~~and a pharmaceutically acceptable carrier~~ in size.

90. (Currently amended) A pharmaceutical composition comprising ondansetron hydrochloride in particle form ~~solid state~~ and a pharmaceutically acceptable carrier, wherein the ondansetron hydrochloride in particle form has ~~with a particle size distribution of~~ 100% of the particles ~~particle size~~ below about 100 microns ~~and a pharmaceutically acceptable carrier~~ in size.

91. (Currently amended) A pharmaceutical composition comprising ondansetron ~~Ondansetron~~ hydrochloride in particle form ~~solid state~~ and a pharmaceutically acceptable carrier, wherein the ondansetron hydrochloride in particle form has ~~with a particle size distribution of~~ 100% of the particles ~~particle size~~ below about 50 microns ~~and a pharmaceutically acceptable carrier~~ in size.

92-93. (canceled)